510(k) SUMMARY

MAY 12 2008

SUBMITTED BY:

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CONTACT NAME: Janine Matlak, Regulatory Affairs Specialist

DATE PREPARED: April 4, 2008

DEVICE TRADE NAME: Doripenem 10µg, BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks

DEVICE COMMON NAME: Antimicrobial Susceptibility Test Disks

DEVICE CLASSIFICATION: 21 CFR§866.1620, Class II (Product Code JTN), Susceptibility Test Disks, Antimicrobial

PREDICATE DEVICE: Other BBL™ Sensi-Disc™
(eg, Ciprofloxacin 5 µg, BBL™ Sensi-Disc™)

INTENDED USE:

Antimicrobial Susceptibility Test Disks are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Doripenem 10µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Doripenem of a wide range of bacteria, as described in the "Indications for Use" section. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer and received FDA approval under NDA Number 22-106.

510(k) SUMMARY

Indications for Use:

Use of Doripenem 10µg BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Doripenem. The concentration of 10µg has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA approved drug insert for this antimicrobic.

Active *In Vitro* and in Clinical Infections Against:

Aerobic facultative Gram-positive microorganisms
Streptococcus constellatus
Streptococcus intermedius

Aerobic and facultative Gram-negative microorganisms
Acinetobacter baumannii
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

Active *In Vitro* Against:

Aerobic and facultative Gram-positive microorganisms
Staphylococcus aureus – (methicillin-susceptible isolates only)
Streptococcus agalactiae
Streptococcus pyogenes

Aerobic and facultative Gram-negative microorganisms
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca
Morganella morganii
Serratia marcescens

DEVICE DESCRIPTION:

Doripenem10µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Doripenem supplied by the drug manufacturer. Each Doripenem disk is clearly marked on both sides with the agent and drug content. Doripenem cartridges each contain 50 impregnated disks that are packed as either a single cartridge in a single box, or in a package containing ten cartridges. Doripenem disks are used for semi-quantitative *in vitro* susceptibility evaluations by the agar diffusion test method.

Agar diffusion susceptibility methods employing dried filter paper disks impregnated with specific concentrations of antimicrobial agents were developed in the 1940s. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the Clinical and Laboratory Standards Institute (CLSI) [Formerly National Committee for Clinical Laboratory Standards (NCCLS)] and is periodically updated.

DEVICE PRINCIPLE:

Disks containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *Haemophilus influenzae* or Mueller Hinton Agar with 5% Sheep Blood for *Streptococcus* species] inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the disks are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. The categorical interpretation [susceptible (S), intermediate (I), or resistant (R)] for the organism being tested with the antimicrobial agent is made by comparing zone diameters to those found in the respective organism tables of CLSI/NCCLS Document M2 ("Performance Standards for Antimicrobial Disk Susceptibility Tests) and of CLSI/NCCLS Document M100 ("Performance Standards for Antimicrobial Susceptibility Testing").

DEVICE COMPARISON:

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks – Doripenem 10µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- Both methods are for antimicrobial susceptibility testing using paper disks impregnated with an antimicrobial agent.
- Both methods have the same intended use.
- Both methods provide the user with antimicrobic minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations (S/I/R) using the measured zone diameters against CLSI/NCCLS Approved Standards M2 and M100.
- Both methods use pure cultures of bacterial isolates.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Doripenem 10µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Doripenem 10µg is a susceptibility test that uses disks impregnated with the antimicrobic Doripenem at a concentration of 10µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg is a susceptibility test that uses disks impregnated with the antimicrobic Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk – Doripenem 10 µg is a susceptibility test used to test a different battery of microorganisms than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Ciprofloxacin 5 µg.

SUBSTANTIAL EQUIVALENCE TESTING DATA:

See the Doripenem drug package insert, "Susceptibility Test Methods: Diffusion Techniques" (Appendix 1).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Janine Matlak
Regulatory Affairs Specialist
BD Diagnostic System
Benton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

MAY 12 2008

Re: k080998
Trade/Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk, Doripenem 10µg
Regulation Number: 21 CFR § 866.1620
Regulation Name: Antimicrobial Susceptibility Test Disc
Regulatory Class: II
Product Code: JTN
Dated:
Received:

Dear Ms. Matlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (K080998):

Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Doripenem10µg

Indications for Use:

Use of Doripenem 10µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Doripenem. The concentration of 10µg has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA approved drug insert for this antimicrobic.

Active *In Vitro* and in Clinical Infections Against:

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Streptococcus constellatus
Streptococcus intermedius

Aerobic and facultative Gram-negative microorganisms
Acinetobacter baumannii
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

The safety and efficacy of doripenem in treating clinical infections due to these microorganisms has not been established in adequate and well-controlled clinical trials - Active *In Vitro* Against:

Aerobic and facultative Gram-positive microorganisms
Staphylococcus aureus – (methicillin-susceptible isolates only)
Streptococcus agalactiae
Streptococcus pyogenes

Aerobic and facultative Gram-negative microorganisms
Citrobacter freundii
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca
Morganella morganii
Serratia marcescens

Prescription Use __√__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie L. Poole

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K080998